SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew TWINFIX PK FP Suture Anchor

Date Prepared: December 12, 2007

MAR - 4 2008

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover MA, 01810

B. Company Contact

Deana Boushell

Principle Regulatory Affairs Specialist

Phone: (508) 337-4036

FAX: (508) 261-3620

C. Device Name

Trade Name:	TWINFIX PK FP Suture Anchor
Common Name:	Fastener, fixation, non-degradable, soft tissue
Classification Name:	Fastener, fixation, non-degradable, soft tissue

D. Predicate Devices

The Smith & Nephew TWINFIX PK FP Anchor is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Arthrex® PushLock™

E. Description of Device

The TWINFIX PK FP Anchor is a suture anchor manufactured from PEEK polymer. The pound in anchor is not preloaded with suture, incorporates a two piece anchor body and faciliates arthroscopic repair of soft tissue to bone. The

design allows the surgeon to adjust the tension on the tissue intraoperatively and secure the repair.

F. Intended Use

The Smith & Nephew TWINFIX PK FP Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Rotator cuff repair, Bankart repair. Slap lesion repair, Biceps tenodesis, Acromio-Clavicular separation, Deltoid repair, and Capsular shift or Capsulolabral reconstruction.

Foot/Ankle: Lateral stabilization, Medial stabilization, Achilles tendon repair, Hallux valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair.

Knee: Medial collateral ligament repair, Lateral collateral ligament repair, Patellar tendon repair, Posterior oblique ligament repair, Illoiotibial band tenodesis.

Hand/Wrist: Scapholunate ligament reconstruction, Ulnar collateral ligament reconstruction, Radial collateral ligament reconstruction.

Elbow: Biceps Tendon reattachment, Ulnar or radial collateral ligament reconstruction.

G. Comparison of Technological Characteristics

The Smith & Nephew TWINFIX PK FP Suture Anchor is substantially equivalent in design, materials, function and intended use to the Arthrex® PushLock™ suture anchor, cleared in K051219. The proposed and the predicate devices both have the same intended use, indications for use, anchor material.

H. Summary Performance Data

The performance testing conducted demonstrates substantial equivalence to the Arthrex® PushLock™ suture anchor, cleared in K051219 . The testing also demonstrates that the differences in the new device and the predicate device do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc., Endoscopy Division
% Ms. Deana Boushell
Regulatory Affairs Specialist
150 Minuteman Road
Andover, MA 01810

MAR - 4 2008

Re: K073509
Trade/Device Name: Twinfix PK FP Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, JDR
Dated: December 12, 2007
Received: December 13, 2007

Dear Ms. Boushell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

§I.D

Indications for Use

510(k) Number (if known): K073509

Device Name: Smith & Nephew TWINFIX PK FP Suture Anchor

Indications For Use:

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Prescription Use ___x_____ AND/OR Over-The-Counter Use ___No

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for M.C.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073509